

# **Exhibit 6**

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : MDL NO. 2327  
PELVIC REPAIR SYSTEM, :  
PRODUCTS LIABILITY :  
LITIGATION :  
THIS DOCUMENT RELATES TO ALL CASES

- - -

AND VARIOUS OTHER CROSS-NOTICED ACTIONS  
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- - -

August 20, 2013

- - -

Videotaped deposition of DANIEL J. SMITH taken pursuant to notice, was held at the law offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, beginning at 9:07 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public for the State of New Jersey.

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1 A. I would imagine they were.

2 Q. When was the first time you found out  
3 that the mesh for -- used in TVT Classic frayed?

4 A. Probably when I worked with the mesh  
5 in the 2001 time frame.

6 Q. So when you first started working on  
7 mesh products used for stress urinary incontinence,  
8 you learned and became aware that the mesh used in  
9 the product would fray?

10 A. I was aware of it. I think it was --  
11 when you cut fabric, it's typical that pieces would  
12 come off and were put -- the pieces that would come  
13 off that you're calling fraying are obviously much  
14 smaller than the mesh itself that we're putting in.

15 Q. Well, would you lose some portion of  
16 the implant, it would essentially come apart,  
17 wouldn't it?

18 A. No, not necessarily, since the design  
19 of the weave itself would not let that happen,  
20 the -- it was just the fraying was on the outer  
21 edges.

22 Q. It would lose volume of particles,  
23 wouldn't it?

24 A. Minor, yes.

25 Q. Minor? Is that your word, minor?

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1           A.           You just lose a few pieces of small  
2 lengths of fiber.

3           Q.           When you found out this was happening  
4 in 2001, did you go back and ask somebody who had  
5 been there previously, did we intend for this to  
6 happen?

7           A.           I don't recall that I had a general  
8 conversation about that. I know it was a known --  
9 it was known to us. It was known to our  
10 competitors.

11          Q.           And that would sometimes result in  
12 the product having sort of a jagged edge look,  
13 wouldn't it?

14          A.           Whether it frayed or not, the  
15 product -- the mesh had a jagged edge look primarily  
16 as part of its fixation. It was sometimes referred  
17 to as the Velcro effect.

18          Q.           Now, when this really became an issue  
19 with physicians is when you went to the TVT Blue,  
20 isn't it?

21          A.           It became I think an issue maybe  
22 prior to that or during that. Blue made it more  
23 visible. But competitors would stretch our mesh  
24 beyond the elastic limits of the mesh, or the usable  
25 limits of the mesh, on black paper even when it was

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1 clear.

2 Q. Well, it didn't have to be stretched  
3 beyond the usable limits for it to fray, did it?

4 A. Typically, yes.

5 Q. So it was only if it was misused that  
6 it frayed?

7 A. Yeah. If you didn't -- if you didn't  
8 stretch it, the pieces would have stayed in place.

9 Q. Is the natural use of this product,  
10 the ordinary course of using the product, it would  
11 be stretched enough to have particle loss, wouldn't  
12 it?

13 A. Yes.

14 Q. If you -- let me show you what I'm  
15 going to mark as -- or what previously has been  
16 marked as Exhibit Number 365.

17 Do you see that this is an e-mail  
18 chain that starts with an e-mail from Richard Hu to  
19 a number of individuals back in April of 2001?

20 A. Yes.

21 Q. And do you see where it says, in the  
22 first e-mail, April 23, 2001 at 2:37 p.m., "Dr. Alex  
23 Wang provided some valuable recommendation regarding  
24 TVT when I met with him last week"?

25 And do you see where down at the

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1 bottom of the page it says, "The width of tape is  
2 not consistent. Some portion is wider than  
3 1.1 centimeter and some narrower. Dr. Wang  
4 suggested we improve our manufacturing process to  
5 make sure the wide is consistent. Or, we have to  
6 prove there is no clinical impact because of the  
7 width variance"? Do you see that?

8 A. Yes.

9 Q. If you go to the page before that,  
10 actually, two pages -- yeah, one page before that,  
11 do you see where there is an e-mail in the middle of  
12 the document from Richard Hu to Laura Angelini  
13 saying, "Hi Laura, Thank you for the help in  
14 advance. Below are picture files which show the  
15 uneven width and serious fraying edge. You might  
16 want to show the pictures" of this -- "if this is  
17 discussed." Right?

18 A. I'll take your word for it. I'm just  
19 trying to find it. I'm sure it does.

20 Q. It's the middle of the page that's  
21 page 475.

22 A. Yes.

23 Q. And then Laura Angelini writes on the  
24 bottom of page 474, "Dear All, I would like you to  
25 read the correspondence here below. Dr. Alex Wang

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1 from Taiwan, one of the most experienced TVT users  
2 in the world, has recently encountered some  
3 difficulties because of inconsistent tape width of  
4 our TVT. I enclose here below the pictures he has  
5 taken (important, product not used! only opened!)  
6 as well as the message containing his comments. I  
7 think this is not an acceptable tape configuration.  
8 I discussed this with Dieter Engel and he suggested  
9 to forward this to the TVT-L team for improving  
10 during development of the blue tape." Do you see  
11 that?

12 A. Yes.

13 Q. And what was the TVL -- TVT-L team?

14 A. I'm not sure who all was on the team,  
15 but it was a team that was put together to create  
16 the TVT mesh that's blue.

17 Q. Okay.

18 Then you see the next page or the  
19 page 2 of the document, there's an e-mail from  
20 Martin Weisberg in the middle of the page.

21 A. Let me go back. 73?

22 Q. Yes.

23 Dated June 4, 2001, saying, "Dr.  
24 Wang's suggestions are good and it is not the first  
25 time we have heard them or thought about

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1 implementing them. I don't think we have any idea  
2 whether the tape inconsistencies are clinically  
3 significant or not, however the appearance of the  
4 tape in the appended pictures certainly gives the  
5 impression of inconsistent manufacturing and/or  
6 quality control." Do you see that?

7 A. That's what he said.

8 Q. Did you come to work on TVT products  
9 shortly after that?

10 A. It was after this, yes.

11 Q. Look at what I'm going to hand you  
12 next, which has previously been marked as  
13 Exhibit Number 531.

14 Do you see where this is dated  
15 November 18, 2003, and it's to the file from three  
16 individuals.

17 How do you pronounce the first  
18 individual's name?

19 A. They were cc'd. It's not from them.  
20 But it's Mosaddeq Hossain, Gene Kammerer and Brian  
21 Luscombe.

22 Q. You're correct, they were cc'd on  
23 this. It was actually written by Marty Weisberg.  
24 Correct?

25 A. Correct.

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1           Q.       And he says in this document, "This  
2   note to file will address complaints of TVT  
3   Tension-free Support for Incontinence mesh fraying  
4   during placement. Since introduction of the device  
5   in 2000, there have been a total of 58 complaints of  
6   fraying. Fraying is inherent in the design and  
7   construction of the product. The application of  
8   tension exacerbates this issue. When the mesh  
9   frays, several events occur: the mesh elongates in  
10  places; the mesh narrows in places; and small  
11  particles of Prolene might break off." Do you see  
12  that?

13           A.       That's what he wrote.

14           Q.       So what Dr. Weisberg is saying here  
15  is, it's just inherent in the design of this  
16  product. Right?

17           A.       He says that, as well as that fraying  
18  does not affect the safety or effectiveness of the  
19  device and they will not pursue it at this time.

20           Q.       Right.

21                    We just saw an e-mail from him back a  
22  few months before in which he said, I don't know  
23  whether it has clinical significance or not. Do you  
24  remember that?

25                    MR. HUTCHINSON: Object to form.

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1 THE WITNESS: Yes. In 2001, I think.

2 BY MR. BLIZZARD:

3 Q. And so here in 2003, he's saying,  
4 well, I don't think it has clinical significance.  
5 Right?

6 MR. HUTCHINSON: Object to form.

7 THE WITNESS: I'd have to read the  
8 whole e-mail and we'd have to talk to Marty as to  
9 what changed his position, but he did.

10 BY MR. BLIZZARD:

11 Q. What studies are you aware of that  
12 were ever done in animals or humans to determine the  
13 clinical significance of this fraying?

14 A. I am not aware.

15 Q. Do you know, you know, when particles  
16 break off of a medical implant, sometimes that's  
17 call debris? Have you heard of that before?

18 A. Not in this case.

19 Q. Well, I understand you may not have  
20 heard it in this case, but when you've got --

21 A. Let me rephrase it. I've never heard  
22 it called debris, but, I mean, I...

23 Q. Do you know anything about  
24 biomaterial science?

25 A. A little bit. There's another --

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1 other folks on the team that deal with that aspect  
2 of it.

3 Q. You know that implants are a foreign  
4 body?

5 A. Yes.

6 Q. And they evoke foreign body  
7 responses. Correct?

8 A. To a degree, yes.

9 Q. So they're not inert, are they?

10 A. They're tested for their inertness or  
11 foreign body response to be acceptable or not  
12 acceptable.

13 Q. They have a foreign body response?

14 A. Yes, they do. Yes, they do.

15 Q. The body produces cells in response  
16 to an implant being put in the body. Correct?

17 A. Yes.

18 Q. And if you have more particles  
19 flaking off of the implant, you're going to have  
20 typically more of a foreign body response, aren't  
21 you?

22 MR. HUTCHINSON: Object to form.

23 THE WITNESS: I would say that would  
24 be an incorrect statement, because if you lost  
25 particles, then you would actually have less

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1 material. So, I mean, in this particular case, the  
2 particles are a minute portion of the mesh that's  
3 being implanted. So the foreign body response of a  
4 mesh that's half an inch wide, far greater mass than  
5 a few particles on the edge.

6 BY MR. BLIZZARD:

7 Q. Well, I mean, if those particles  
8 flake off once they're in the body, those particles  
9 create an additional potential for foreign body  
10 response, don't they?

11 A. No. If they didn't break off, they  
12 would have the same foreign body response if they  
13 stayed attached. So there is no difference whether  
14 they're attached or not attached if there's a  
15 foreign body response.

16 Q. So what expert analysis do you rely  
17 on for that statement?

18 A. Just common sense.

19 Q. So that your position is -- and I  
20 guess, is it the company's position that if the  
21 implant is intact and stays intact that there's  
22 going to be a bigger foreign body response to that  
23 than if parts of the implant come off of it --

24 MR. HUTCHINSON: Object to form.

25 BY MR. BLIZZARD:

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1 Q. -- in the body?

2 MR. HUTCHINSON: Object to form.

3 Counsel, I remind you, this is not a 30(b)(6)  
4 deposition. It is fact witness only.

5 BY MR. BLIZZARD:

6 Q. Well, withdraw the company's  
7 position.

8 Is it your position that if there's  
9 going to be a bigger response, foreign body response  
10 to an intact implant than an implant that's losing  
11 particles after implantation?

12 A. So let me try to explain my original  
13 statement.

14 You were asking if you'd have greater  
15 foreign body response if you lost a particle. So my  
16 answer was that if you have a mass of X and we know  
17 that that mass of X has an acceptable foreign body  
18 response in the body, because that's been tested, if  
19 you have a particle that separates and is still in  
20 the body, you still have that same mass. And if a  
21 particle or two fell off, then you would have  
22 potentially slightly less, but the mass is so much  
23 greater in terms of the mesh that's being implanted  
24 than this small particle that perhaps fell off.

25 Q. The foreign body response created to

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1 a particular implant is not dependent solely on the  
2 mass, is it?

3 A. No. But since we're speaking of TVT,  
4 I was only referring to that. If you changed the  
5 material, you'd have a different foreign body  
6 response.

7 Q. Surface characteristics of the  
8 implantable material affect the foreign body  
9 response, don't they?

10 A. They could have an effect.

11 Q. And so this was intended originally  
12 to be a single implant, one designed to be implanted  
13 in the human body with certain surface  
14 characteristics. Correct?

15 A. Like I indicated, it was before my  
16 time, but the edges of the mesh have always been  
17 designed to be sticking out of the mesh and have a  
18 Velcro effect for fixation.

19 Q. And was it part of the design to let  
20 there be debris or fraying or particle loss of these  
21 implants? Was that part of the design?

22 MR. HUTCHINSON: Object to form.

23 THE WITNESS: Again, since I was not  
24 part of that development years before I joined, and  
25 I'm sure they knew that they had particle loss, that

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1 was -- I would have to assume that would be part of  
2 the design.

3 BY MR. BLIZZARD:

4 Q. Well, let me just ask, are you aware  
5 of any studies in humans, animals, on the pathology  
6 of foreign body response to these frayed particles?

7 A. No. It's, again, not -- you know, it  
8 wouldn't be something that I would have seen, and  
9 I'm not sure if -- what was done on that.

10 Q. Well, you were intimately involved in  
11 this issue, weren't you?

12 A. I was involved in some of the issues  
13 with particle loss, yes.

14 Q. You were concerned about the fact  
15 that when they went to TVT Blue, that these blue  
16 particles were visible to physicians. You were  
17 concerned about that, weren't you?

18 A. Yes.

19 Q. Let me just show you or hand you  
20 what's been marked as Exhibit Number 366.

21 If you look at the e-mail at the top  
22 of page 1, is this an e-mail written by you?

23 A. Yes.

24 Q. And this is dated February 27, 2004.  
25 Correct?

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1 A. Yes.

2 Q. You wrote it to Janice Burns; is that  
3 right?

4 A. Yes.

5 Q. What was Janice Burns' position with  
6 the company?

7 A. Marketing.

8 Q. And the subject is, it says,  
9 "Important: 2 TVT Complaints concerning allegedly  
10 brittle mesh." Do you see that?

11 A. Yes.

12 Q. You write in the first sentence, "I  
13 believe this MUST," and must is capitalized, all  
14 caps. Right?

15 A. It is.

16 Q. So you were emphatic about this.  
17 Right?

18 A. It was my position.

19 Q. "I believe this MUST be discussed at  
20 a Ronnie, Alan, Laura, Barbara" -- how do you  
21 pronounce that next name?

22 A. I couldn't tell you right now. I'm  
23 not sure what her role was at the time.

24 Q. -- "Pryia level ASAP."

25 What level would that be?

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1           A.           Most of those were vice presidents.  
2   I'm not sure, Pryia, what her level was, but she  
3   probably was a vice president.

4           Q.           So you're saying this must be  
5   discussed at the vice president level immediately.  
6   Right?

7           A.           That's what I said.

8           Q.           "This is not new, and was exactly the  
9   original issue that stopped TVT blue for months.  
10   The fix (I'm not sure how to complete) is to cut the  
11   mesh using ultrasonics, but it has not been  
12   validated and I'm not sure where it sits on the  
13   Operations priority list. I recall it was scheduled  
14   for mid to end of 2004 (last year) and" -- how do  
15   you pronounce that city in Germany?

16          A.           Neuchatel.

17          Q.           -- "will have to do this along with  
18   TVT Next, D'Art, the sheath splitting, and TVTO  
19   scale up.

20                        "I believe that the board has to set  
21   a directive that can be filtered down to the reps,  
22   saying its OK."

23                        So you're asking that the board  
24   actually set a directive here indicating that it's  
25   okay for these particles to be fraying. Right?

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1           A.           It was my opinion coming in that --  
2   and what Ethicon gives us the authority to do is to  
3   speak, you know, our concerns. And I raised my  
4   concern up to the vice president level and wanted  
5   them to be aware of it.

6           Q.           Okay.

7                        "Saying its OK and its not an issue,  
8   same as TVT clear except you can see it."

9                        So essentially you had the same issue  
10   with TVT clear, but you couldn't see it until you  
11   started making the implant in blue. Correct?

12          A.           Not correct. As I indicated, you  
13   know, our competitors would stretch the clear over  
14   black paper and you could see it as well.

15          Q.           It says, "By the way you can also see  
16   it in the package as the pieces fall out of the  
17   sheath splits!"

18                        So actually, you can see these  
19   particles coming off in the package. Right?

20          A.           They're minor, as I indicated  
21   earlier.

22          Q.           Now, what does the next sentence say?  
23   Could you read that out loud for me?

24          A.           "This is not going" to go "away  
25   anytime soon and" our "competition will have a field

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1 day, major damage control...needs to start to  
2 educate the reps and surgeons UPFRONT as they will  
3 see" the "BLUE shit and it is OK. This is why I  
4 wanted to launch TVTO in clear!!!!!"

5 Q. So basically you're saying they're  
6 going to see this blue stuff and that it's okay, and  
7 then you say, "This is why I wanted to launch TVTO  
8 in clear!!!!!"

9 So you wanted to make sure it was in  
10 clear so it wouldn't be seen. Right?

11 MR. HUTCHINSON: Object to form.

12 THE WITNESS: No. Well, yes and no.  
13 So TVT-O was being launched as -- originally as a  
14 mechanically cut product, which is -- a mechanically  
15 cut product has the fraying associated with it,  
16 which had much clinical evidence with it. And we  
17 were working at the same time on putting in either  
18 ultrasonics or laser cutting. So it was my opinion,  
19 and I, you know, felt that if we were going to do  
20 that, we would eliminate the particle loss by  
21 completing the activities that we're going to do  
22 first. Otherwise, we'd have to explain it. And  
23 perhaps it's a poor choice of words in some of it,  
24 but it was my opinion.

25 BY MR. BLIZZARD:

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1 Q. So you didn't want to have to explain  
2 it to the doctors?

3 A. We will. Again, it's Marty's e-mail  
4 saying that it has no clinical relevance.

5 Q. Well, you didn't want to have to  
6 report it as a complaint even when doctors said,  
7 hey, we're seeing this stuff coming off the implant,  
8 you didn't even want to report it and log it as a  
9 complaint, did you?

10 MR. HUTCHINSON: Object to form.

11 THE WITNESS: I don't believe I said  
12 that here.

13 BY MR. BLIZZARD:

14 Q. Let me show you what I'm going to  
15 mark as Exhibit 2154.

16 - - -

17 (Deposition Exhibit No. T-2154,  
18 E-mail chain, top one dated 02 Mar 2004,  
19 Bates stamped ETH.MESH.00865322 and  
20 ETH.MESH.00865323, was marked for  
21 identification.)

22 - - -

23 BY MR. BLIZZARD:

24 Q. Do you see where it says at the  
25 bottom of page 1 -- actually, if you go over to the

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1 next page, page 2, there's an e-mail, it says, "Dear  
2 all." Do you see that?

3 A. Uh-huh.

4 Q. It looks like it's authored by Steve  
5 Bell; is that correct?

6 A. He was the director of marketing for  
7 Europe.

8 Q. Do you see where it says, "Dear all,  
9 As more and more customers now move to TVT Blue and  
10 TVT-O with blue mesh you may sometimes hear. 'I can  
11 see small blue pieces come off the mesh! What's  
12 wrong." And then he writes, "KEY POINTS. Gynecare  
13 Blue TVT mesh and Gynecare Clear TVT mesh are  
14 exactly the same." Do you see that?

15 A. Yes.

16 Q. That's true, isn't it?

17 A. Except for the color.

18 Q. So it was easier to see the blue  
19 particles than it was the clear particles. Right?

20 A. The reason for going to blue was so  
21 that the surgeon could see it under the urethra.

22 Q. Right.

23 But they also could see the fraying  
24 easier?

25 A. Yes.

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1           Q.       So as "The same number of particles  
2 came off the clear mesh when it was stretched --  
3 It's just that you see them against the tissues and  
4 skin more when they are blue. - This is no  
5 different to what has happened for the past 7 years  
6 with TVT." Do you see that?

7           A.       Which is, again, supportive of  
8 there's no safety or clinical issue.

9           Q.       So it says in item number 3,  
10 "Reassure your doctors that this is part of the  
11 success of TVT. The way we have cut the mesh makes  
12 the edges softer and we feel this has been a crucial  
13 success factor in TVT. Reassure them that PROLENE  
14 is proven to be inert and there are hundreds of  
15 papers going back 25 years to reinforce this point.  
16 These particles will not cause any problem." Do you  
17 see that?

18          A.       That's what he wrote.

19          Q.       Okay.

20                   And these were representations made  
21 by the company to physicians at Steve Bell's  
22 recommendation. Right?

23          A.       I would assume, yes.

24          Q.       You believed them to be true, didn't  
25 you?

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1 A. I believe it, yes.

2 Q. You have no problem making these  
3 representations to physicians, do you?

4 MR. HUTCHINSON: Object to form.

5 THE WITNESS: I have no problem  
6 discussing them, that Prolene has the  
7 characteristics that are listed here, that it is --  
8 you know, the body will accept Prolene.

9 BY MR. BLIZZARD:

10 Q. You have no problem making the  
11 representation that Prolene is inert?

12 A. I think inert, in the word that is  
13 being used here, I think I have stated that it will  
14 not have any -- a negative tissue reaction that  
15 would be bad. I mean, Prolene -- this is the same  
16 Prolene that's used in cardiovascular surgery and  
17 blood vessels, heart surgeries. It's been -- and  
18 that's where the 25 years comes from. So when you  
19 take a suture and you take a -- and stitch a vessel  
20 back together with small pieces of suture, you  
21 basically have small pieces of polypropylene. So,  
22 in essence, that's been going on for years.

23 Q. As an engineer who's worked for the  
24 company for years, again, you believe and have  
25 represented to customers of the company and to other

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1 people within the company that polypropylene, when  
2 inserted in the human body, is inert?

3 A. It will not have a negative foreign  
4 body response.

5 Q. Is that always the case? There's no  
6 tissue reaction that's negative ever?

7 A. Negative in terms of the fact that  
8 there's always a foreign body response, but the body  
9 then heals itself.

10 Q. On every occasion where it's  
11 implanted in a human, it has that response?

12 A. You're putting words in my mouth.

13 Q. Well, I'm asking.

14 A. If you have an infection, obviously,  
15 that would be the case.

16 Q. Well, it can cause --

17 MR. HUTCHINSON: Hold on just a  
18 minute, Counsel. Let the witness finish his answer,  
19 please.

20 THE WITNESS: I am obviously trying  
21 to explain, you know, polypropylene has been used.  
22 Steve Bell, who wrote this e-mail, uses it as inert.  
23 Inert can add the connotation that there will be no  
24 response at all. I don't believe that that's -- I  
25 mean, I think everyone understands that when you put

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1 anything in the body, there is some degree of  
2 foreign body response.

3 BY MR. BLIZZARD:

4 Q. So using inert in a technical sense,  
5 this is false, isn't it?

6 A. I probably would have used a  
7 different word.

8 Q. But this is what Steve Bell was  
9 telling the salespeople to go out and tell doctors.  
10 Right?

11 A. It appears that way.

12 Q. Now, by the way, when you put  
13 polypropylene, mesh polypropylene from these  
14 implants in the body, there is a foreign body  
15 response. Right?

16 A. To an acceptable degree.

17 Q. And it can become a chronic foreign  
18 body response, can't it?

19 A. I'm sure if there's conditions exist,  
20 it could, yes.

21 Q. It could involve macrophages and  
22 giant cells. And when that happens, we're actually  
23 getting an immune response to the product, aren't  
24 we?

25 MR. HUTCHINSON: Object to form.

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1 THE WITNESS: You're -- you are  
2 getting a little bit outside of my education in  
3 terms of that, so if -- you know, you probably would  
4 be best talking to other folks around the immune  
5 responses and cell responses.

6 BY MR. BLIZZARD:

7 Q. Let me show you what -- well, before  
8 we get to that next exhibit, let me talk about this  
9 one.

10 If you look at the -- below the  
11 summary, do you see where Steve Bell says --

12 A. Are we back on the document? I put  
13 it away.

14 Q. Yes, I'm sorry. I'm sorry. I wasn't  
15 quite finished with it.

16 Do you see where it says, "Be  
17 proactive (the competition will try and target this!  
18 Especially BARD as they have a sealed edge tape) and  
19 remind your customers it is the same as clear. It  
20 is a proven safe implant (in the blue format over  
21 100,000 have been implanted world wide). Remind  
22 them of the benefits of blue mesh. Remind them it  
23 is inert PROLENE with over 25 years of use. Remind  
24 them of our wealth of clinical data with ultra low  
25 complication rates." Do you see that?

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1 A. That's what he wrote.

2 Q. These were all suggestions that were  
3 made for salespeople to communicate. Right?

4 A. I don't understand where the -- and  
5 don't see the "here all," so I'm not sure where all  
6 this went to. But being Steve is in marketing, I'm  
7 sure he was communicating it to marketing.

8 Q. You would expect these  
9 representations -- these recommendations by Steve to  
10 be carried out, wouldn't you?

11 A. I would say yes.

12 Q. If you look at an e-mail on the  
13 bottom of the first page, do you see it's from you  
14 to Charlotte Owens, who is a medical director for  
15 the company at the time?

16 A. Uh-huh, yes.

17 Q. And it says, "Subject: Reminder on  
18 BLUE mesh!" The "Importance" is indicated as  
19 "High." Right?

20 A. Yes.

21 Q. It says, "Charlotte, With regard to  
22 our discussion yesterday around logging customer  
23 complaints, I just wanted to keep you up to date and  
24 informed. I do not know how these questions are  
25 being logged or if they need to be? You may want to

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1 discuss this with Janice to better understand the  
2 customer situation.

3 "This is a marketing communication  
4 regarding 'BLUE' TVT mesh. There has been some  
5 customer questions raised about the blue" package --  
6 "the blue particles again (the same as when it was  
7 released in the states)." Do you see that?

8 A. Yes.

9 Q. Then Charlotte Owens responds to your  
10 e-mail saying, "If a patient is affected then it  
11 constitutes a complaint. If it is just physicians  
12 feeling a certain way about it then we don't log it  
13 as a complaint." Do you see that?

14 A. Oh, I'm sorry, I went down and not  
15 up. Yes.

16 Q. So Charlotte Owens is saying, look,  
17 if it's just a physician reporting that this blue  
18 stuff is coming off, we don't log that as a  
19 complaint?

20 A. That's what she said.

21 Q. Okay.

22 A. But we do know that they were logged  
23 as complaints in some cases. Depending how they  
24 came in, they get logged, depending on the category  
25 they come in.

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1           Q.           Let me show you what I'm going to  
2 mark as Exhibit Number 2155 to your deposition.

3                               - - -

4                               (Deposition Exhibit No. T-2155,  
5 E-mail chain, top one dated 09 Mar 2004,  
6 Bates stamped ETH.MESH.00863405 through  
7 ETH.MESH.00863407, was marked for  
8 identification.)

9                               - - -

10 BY MR. BLIZZARD:

11           Q.           You see this is an e-mail at the  
12 bottom of the page from you dated March 9, 2004?

13           A.           On the second page?

14           Q.           It starts at the bottom of the first  
15 page.

16           A.           Yes.

17           Q.           Do you see it's dated March 9th and  
18 it's "Importance: High," "Complaint TVTO"? Do you  
19 see that?

20           A.           Yes.

21           Q.           And the body of the e-mail starts  
22 over on the next page.

23                               Do you see where it says, "There are  
24 seven complaints and 6 are for the BLUE mesh  
25 fraying, the seventh will be reviewed to understand

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1 what happened. Steve Bell has issued an information  
2 sheet (below) to the sales force last week however I  
3 believe there may be a need for additional damage  
4 control if we do not want to impact TVT-O sales!"

5 So there was concern about this blue  
6 stuff impacting sales. Correct?

7 A. Yes. From an R&D person.

8 Q. It says, "What was done, when the USA  
9 converted to BLUE mesh? Will BLUE mesh fraying  
10 complaints be a measure of success (in a negative  
11 way) for TVTO? Should this be addressed on a GLOBAL  
12 basis? What should" -- and I don't know why I can't  
13 remember how to pronounce that.

14 A. Neuchatel.

15 Q. -- "Neuchatel's standard complaint  
16 reply look like and how will this stock answer be  
17 perceived by the surgeons?"

18 These were all questions that you  
19 had. Right?

20 A. I did.

21 Q. And then if you look over on the next  
22 page, do you see where Brian Luscombe responds to  
23 your e-mail and sends it to a bunch of other people  
24 on the same day?

25 A. Are you talking about the first page?

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1 I'm not seeing where you're looking at.

2 Q. Go to the first page of the document.  
3 There's an e-mail from Brian Luscombe, March 9, 2004  
4 to you and others. Do you see that?

5 A. Oh, the original one. I'm sorry.  
6 Yes.

7 Q. It says, "Subject: Complaint TVTO.  
8 All, In the US, we proactively discussed the mesh  
9 construction with the physicians to make them aware  
10 that our clear mesh also frays, but that this  
11 fraying is inherent in the construction of our  
12 mesh...we then also reinforce that the open weave  
13 construction of our mesh is likely one of the  
14 critical success factors that has allowed  
15 GYNECARE...to be so successful - having such low  
16 erosion and exposure rates." Do you see that?

17 A. Yes.

18 Q. So basically what Luscombe is saying  
19 is that the physicians were told that this fraying  
20 was actually a benefit to the patient because it was  
21 one of the reasons for low erosion/exposure rates.  
22 Correct?

23 MR. HUTCHINSON: Object to form.

24 THE WITNESS: That would be an  
25 incorrect assumption. When I read this, the saying

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1 is that he was saying that the mesh frays, we know  
2 that. But the mesh is the mesh and is -- the mesh  
3 is what's doing -- solving the SUI. So it's the  
4 mesh itself and the expansion and the elasticity of  
5 that mesh is what's giving us the low exposure and  
6 erosion rates. He's not saying that the particle  
7 loss is low erosion or exposure rates.

8 BY MR. BLIZZARD:

9 Q. Well, you know that a lot of  
10 physicians were not happy with this particle loss,  
11 were they?

12 MR. HUTCHINSON: Object to form.

13 THE WITNESS: I can't answer that. I  
14 know that there was some that complained about it.  
15 There was others and probably more than the ones  
16 that complained about it that didn't complain at  
17 all.

18 BY MR. BLIZZARD:

19 Q. Let me just show you what I've marked  
20 as Exhibit Number 367.

21 You see this is also in the same time  
22 frame, November 10, 2004, from a David Menneret --  
23 I'm sorry, from Sibylle Basso to David Menneret.  
24 "Hello David, Please see the attached letter of  
25 Mister PD Dr. Eberhard (he is one of our most urgent

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1 customers!!!) Hope you understand a little bit" of  
2 "German.

3 "Is there a process on going  
4 concerning the production of the TVT blue tape? Do  
5 you have received any other comments like that one?  
6 Is the problem communicated to the organization...  
7 If not, what could we do?"

8 If you look over at the next page of  
9 this document, you could see there's a letter in  
10 German?

11 A. Yes.

12 Q. Do you read German?

13 A. No, I do not read German.

14 Q. Look down at the below the German --  
15 do you see there's a little picture there of mesh?

16 A. Yes.

17 Q. Does that look like some particle  
18 loss there?

19 A. There has been particle loss on the  
20 edges, yes.

21 Q. And that's not minor particle loss,  
22 is it?

23 MR. HUTCHINSON: Object to form.

24 THE WITNESS: As I indicated, if the  
25 mesh is stretched beyond its elastic limit, you will

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1 get fraying and particle loss more severe.

2 BY MR. BLIZZARD:

3 Q. Well, this e-mail or telefax  
4 communication on page 1 does not indicate that this  
5 doctor is some bozo who stretched this beyond the  
6 limits. This indicates that this guy is one of your  
7 most urgent customers, doesn't it?

8 MR. HUTCHINSON: Object to form,  
9 argumentative.

10 THE WITNESS: I can only look at  
11 what's here. Perhaps he wanted to make a point.

12 BY MR. BLIZZARD:

13 Q. Well, do you expect -- is this  
14 something --

15 This photo of this mesh, this kind of  
16 particle loss, as one of the design engineers for  
17 TVT, is this acceptable?

18 A. Actually, this would be an extreme  
19 case, but the design of the weave for TVT will stay  
20 together if has three wales, and that indicates that  
21 the mesh fraying stops. And it's only the edges  
22 that were cut that actually fray. So the mesh stays  
23 intact in terms of the use of the mesh clinically,  
24 although it perhaps has fraying.

25 Q. So your view is that this mesh, from

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1 a clinical standpoint, is acceptable to put in the  
2 human body?

3 MR. HUTCHINSON: Object to form.

4 THE WITNESS: It's only going to be  
5 my opinion that the mesh, you know, if -- when used,  
6 if stretched to this degree would still work if the  
7 surgeon needed to stretch a mesh in order to make  
8 the woman continent. I have seen Dr. de Leval  
9 stretch mesh perhaps even further than this. And  
10 she was perfectly continent four years later, so...

11 BY MR. BLIZZARD:

12 Q. So you would not have a problem, I  
13 take it, having a mesh product like this, this  
14 product, inserted into someone you knew?

15 A. No.

16 Q. A photograph like this?

17 A. Well, you wouldn't insert this  
18 particular mesh. You would -- you know, this is a  
19 picture of a mesh that someone stretched.

20 Q. It's a picture of mesh that's lost a  
21 lot of particles, isn't it?

22 A. It has narrowed.

23 MR. HUTCHINSON: Object to form of  
24 the last question.

25 BY MR. BLIZZARD:

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1           Q.       Let me show you what I'm marking as  
2 Exhibit Number 369 to your deposition.

3                   Do you see that this is a translation  
4 of Dr. Eberhard's letter of October 18, 2004? Do  
5 you see it says it's a translation of his letter?

6           A.       Yes.

7           Q.       The title says, "TVT tape. Dear  
8 Emilie, Please find attached a TVT tape, which was  
9 used as a demo unit for patients before they have  
10 their operation." Do you see that?

11          A.       Yes.

12          Q.       "Already at the operation it is  
13 embarrassing to see how the tape is crumbling" --

14                   MR. HUTCHINSON: Counsel -- no, we  
15 need to stay on the record.

16                   Is that -- is New Jersey counsel  
17 still participating in this deposition by telephone?

18                   Somebody obviously put us on hold.

19                   Hello? Hello?

20                   I mean, that's obviously distracting,  
21 so we need to fix that. So why don't we go off the  
22 record.

23                   THE VIDEOGRAPHER: The time is now  
24 2:06. This is the end of Disk Number 3. We are  
25 going off the record.

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1 - - -

2 (A recess was taken from 2:06 p.m. to  
3 2:31 p.m.)

4 - - -

5 THE VIDEOGRAPHER: The time is now  
6 2:31. This is the beginning of Disk Number 4. We  
7 are back on the record.

8 BY MR. BLIZZARD:

9 Q. Mr. Smith, when we went off the  
10 record, we were short on tape, we had some disco  
11 music playing and it was hot in here. So I think  
12 all that has been corrected. And so are you ready  
13 to proceed again?

14 A. I am, thank you.

15 Q. I think we were talking about  
16 Exhibit 369, which is the "Translation of PD Doctor  
17 Eberhard's letter of" October 18th of 2004?

18 A. That's correct.

19 Q. I think the first paragraph indicates  
20 that he had been using the unit as a demo model for  
21 patients when they were having -- before they had  
22 their operation. And he says in paragraph 2,  
23 "Already at the operation it is embarrassing to see  
24 how the tape is crumbling. But it gets worse if  
25 there is...stretch on the tape." And he then says,

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1 "It is urgent that Johnson & Johnson quickly produce  
2 a" -- I think he means tape -- "that is" sold "and  
3 weaved" -- "solid and weaved. If not I have the  
4 convenience that the doctors will change the" tapes  
5 "and will get others (from other suppliers)." And  
6 then he says, "I can't understand that no one will  
7 solve" the "problem for such a long time. At the  
8 latest, as the tape has becoming blue, everyone has  
9 realized, that the quality of the tape is terrible.  
10 Please see the pictures of the I-STOP tape of  
11 Hausmann. A tape has to be weaved and should not"  
12 crumble. "Please try one and you will see that the  
13 tape is crumbling." Do you see that?

14 A. This is obviously -- yes, I see it.  
15 It's his opinion, but as I think I indicated that we  
16 didn't know where that mesh came from, but it was  
17 obviously a sample. So somebody was stretching the  
18 mesh.

19 Q. Right.

20 But it --

21 According to him, it was crumbling,  
22 and it looks like it was crumbling, wasn't it?

23 A. Yeah. I mean, people would say that  
24 the particles falling off, that it was crumbling.

25 God bless you.

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1           Q.       If you look at what I'm going to mark  
2 or what's been previously marked as Exhibit Number  
3 974, do you see that this is another document that  
4 has to do with fraying?

5                   If you look over on page 2 of this  
6 document, do you see there's an e-mail from Paul  
7 Parisi dated December 9th of 2004 to a number of  
8 people, including yourself?

9           A.       Yes.

10          Q.       And do you see it says, "To all,  
11 Allison will try to gain...VOC" -- which is voice of  
12 customer, isn't it?

13          A.       Correct.

14          Q.       -- "on Laser Cut Mesh during this  
15 weekend's PROLIFT cadaver lab. Please provide  
16 feedback on the questionnaire below directly to  
17 her." Do you see that?

18          A.       Yes.

19          Q.       So now, over on the first page, you  
20 say -- there's an e-mail from you. Right?

21          A.       There is.

22          Q.       And it says --

23                   This is to Kevin Mahar, who was VP of  
24 sales, wasn't he?

25          A.       Yes, I believe he was.

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1           Q.       And it's December 10, 2004. You say,  
2 "Just a thought with regard to us collecting  
3 information.

4                   "Paul, what was the ruling from our  
5 compliance group regarding us asking  
6 questions/collecting data? Did we have to log  
7 issues as complaints?????" And then you've got a  
8 whole bunch of question marks after that. Right?

9           A.       I do.

10          Q.       It says, "If so, we should do this in  
11 a manner that avoids this issue." Do you see that?

12          A.       Right.

13          Q.       So you were trying to do it in a  
14 manner that avoided logging these issues as  
15 complaints. Right?

16          A.       Incorrect. So you're -- if I could  
17 put this in context. So typically if we -- whenever  
18 we get information, if we were to do a  
19 questionnaire, we should -- and I was questioning  
20 whether we should -- put them in as complaints, even  
21 though they're not complaints, because we're asking  
22 questions. So the question here was to make sure  
23 that we didn't fall into that from a asking  
24 questions perspective that aren't necessarily  
25 complaints that we would then have to put into the

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1 complaint system. It was to ask them in a manner  
2 that, you know, would be appropriate to get the  
3 information and proactively so that we could work on  
4 this issue that people are saying is the fraying  
5 issue and complete the -- you know, move forward.

6 Q. Right.

7 You're saying that we should do this  
8 in a way where we don't have to log it as a  
9 complaint. Right?

10 MR. HUTCHINSON: Object to form.  
11 It's been asked and answered, Counsel.

12 BY MR. BLIZZARD:

13 Q. Isn't that what this is?

14 A. Because a question is not a  
15 complaint. A complaint is when a doctor calls up  
16 and logs a complaint. It's not something that we  
17 say, what are your thoughts on this and now we have  
18 to log it as a complaint because we got their  
19 thoughts.

20 Q. Well, I mean, if you ask the  
21 question, Doctor, do you have any problems with our  
22 implant and they say, well, look, I don't like the  
23 fact that there's blue stuff that comes off this  
24 implant every time I use it, that's a complaint,  
25 isn't it?

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1           A.           It's an opinion. And the complaints  
2 in the complaint system, which is why I'm asking the  
3 question, are those that the doctor picks up the  
4 phone and calls the hotline and puts the complaint  
5 in.

6           Q.           Well, regardless, you reference the  
7 compliance group here. Right?

8           A.           They would make the call as to how we  
9 would -- how we should structure our questionnaire.

10          Q.           Right.

11                       The compliance group is -- that's the  
12 group within the company that keeps you out of  
13 trouble with the FDA. Right?

14                       MR. HUTCHINSON: Object to form.

15                       THE WITNESS: No.

16 BY MR. BLIZZARD:

17          Q.           They make sure you dot your Is and  
18 cross your Ts, don't they?

19                       MR. HUTCHINSON: Same objections.

20                       THE WITNESS: No. They're just one  
21 of the groups. Just the compliance group I'm  
22 speaking of would be the worldwide quality group  
23 that collects the complaint data.

24 BY MR. BLIZZARD:

25          Q.           That's the quality group. Right?

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1           A.           It's a division of the quality group.

2           Q.           So what's the compliance division's  
3     role?

4           A.           When I use compliance here, it was  
5     just a general term, because I was speaking --  
6     worldwide quality is the only one -- I mean, within  
7     the company, people would know what I was talking  
8     about. Worldwide quality, which is part of  
9     compliance, are the ones that collect the data.

10          Q.           Okay. So let's not spend any more  
11     time on that.

12                       If you look up at the top, it looks  
13     like Steve Bell answers your question for you.

14                       Your question was, how do -- if we  
15     should do this in a manner that avoids this issue.  
16     Correct? And he says, "Ask generally about all  
17     meshes. Don't specify our brand."

18          A.           I believe it was a reasonable  
19     question, and I still believe it's a reasonable  
20     question.

21          Q.           Okay.

22                       And that's his answer. Right? The  
23     way we avoid having to log it as a complaint is to  
24     ask it about all meshes rather than specifying the  
25     brand?

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1           A.           He's suggesting that that's what we  
2   do.

3           Q.           Now, at one point, there was a test  
4   that was developed to determine acceptable particle  
5   loss, wasn't there?

6           A.           No. There was a test developed to  
7   determine the differences in particle loss between  
8   laser cut and mechanical cut.

9           Q.           Well, there was a test to look at  
10   implants and the acceptable level of particle loss  
11   that was developed in France, wasn't there?

12          A.           Then I'm speaking of a different one.

13          Q.           Let me show you what's been marked as  
14   Exhibit Number 371.

15                       MR. HUTCHINSON: Counsel, when we say  
16   these are exhibits that have previously been marked,  
17   are we talking about the four days that Dan has  
18   already been deposed; is that correct?

19                       MR. BLIZZARD: I have no idea.

20                       MR. HUTCHINSON: Do you know where  
21   this document came from?

22                       MR. BLIZZARD: It came from the  
23   exhibits. That's all I know. People pull these  
24   exhibits for me and put them in folders and I look  
25   at them.

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1 THE WITNESS: I'm not sure I've seen  
2 this in my prior deposition.

3 MR. BLIZZARD: There you go. The  
4 witness knows more about it than I do.

5 BY MR. BLIZZARD:

6 Q. So it looks like this is an e-mail  
7 that was written by Gene Kammerer to Jacqueline  
8 Flatow. Right?

9 A. Yes.

10 Q. Dated May 9, 2006. Right?

11 A. That's what it says.

12 Q. It says, "Particle loss on TVT."  
13 And this is the same issue we've been  
14 talking about, isn't it?

15 A. By a different individual, but yes.

16 Q. Is Gene Kammerer, he's somebody who  
17 works as an engineer in the company?

18 A. He was. And he was looking at a  
19 project for ultrasonic cutting.

20 Q. The cutting, you mean the laser cut?

21 A. No. Ultrasonic is vibration, sound.  
22 A laser is heat and light.

23 Q. So which one was he working on?

24 A. The ultrasonic.

25 Q. It says, "Jackie, I need some

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1 clarification on the particle loss test. France is  
2 trying to set new standards for the TVT like  
3 products. Particle loss is one of the standards.  
4 They have a test method which shows 8.5% loss for  
5 TVT." Do you see that?

6 A. I see it. I have no idea what the  
7 test method is.

8 Q. But it says 8.5 percent, that's a  
9 pretty big loss of particles, isn't it?

10 MR. HUTCHINSON: Object to form.

11 THE WITNESS: Since it doesn't have a  
12 relative base, it's -- I don't know what the -- what  
13 to tell you.

14 BY MR. BLIZZARD:

15 Q. Okay.

16 "I am challenging their method as too  
17 vigorous. They have since backed off on the  
18 roughness of the test, but TVT still has very high  
19 %. It will fail the test if the test is excepted as  
20 stands and we will not be able to sell in France  
21 next year." Do you see that?

22 A. That's what it says.

23 Q. Did you ever become aware of this  
24 issue?

25 A. Not to my knowledge, no.

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1 Q. Let me show --

2 A. I mean, any test method -- I mean,  
3 you can create a test method. It may not be an  
4 appropriate test method, but if -- and that's why  
5 you would need to see the test method, to understand  
6 what they were trying to do.

7 Q. Well, he says that TVT has a very  
8 high percentage. That's what Gene Kammerer says.  
9 Right?

10 A. It was his choice of words here.

11 Q. Then it's Exhibit 372.

12 Do you see this is another e-mail  
13 from Gene Kammerer dated June 12, 2006?

14 A. Yes.

15 Q. This is written to Sungyoon Rha. Do  
16 you see that?

17 A. Yeah, Sunny.

18 Q. Sunny.

19 What --

20 Where does Sunny work?

21 A. Sunny was in operations, to my  
22 knowledge.

23 Q. In the same group you were in?

24 A. She was in Ethicon as well as in  
25 Neuchatel at some point, but her role was different.

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1 It was not development, it was operations.

2 Q. Do you --

3 A. She would have been on a team.

4 Sorry.

5 Q. Okay.

6 Do you see where it says, "Sunny, In  
7 the test method from the new French standards for  
8 particle loss the difference between TVT and the  
9 competitors is significant. Approximately 10 fold  
10 more for TVT at 8% of the strip falling off. They  
11 do nothing special to the mesh and the test is very  
12 similar to our test, except for the preparation  
13 step." Do you see that?

14 A. That's what he writes.

15 Q. So essentially he's saying in this  
16 e-mail that when you run this test on particle loss  
17 that they've developed in France, which is very  
18 similar to the company's test, there's ten times  
19 more particle loss in the TVT product than the  
20 competitor's product. Right?

21 A. I'd have to read it again in terms of  
22 the company's test. We don't have a test for it, so  
23 I think we're just referring to the French test.

24 Q. It says, "They do nothing special to  
25 the mesh and the test is very similar to our test."

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1 Do you see that?

2 A. I mean, that's what he writes, but  
3 I'm not familiar with what test he was working on  
4 either.

5 Q. Well, regardless, ten times more than  
6 the competitors, that's a huge difference, isn't it?

7 MR. HUTCHINSON: Object to form.

8 THE WITNESS: It's a relative number.

9 If your mesh is constructed differently or has a  
10 different weave, a lot of the competitors' meshes  
11 don't stretch at all, so that would explain why this  
12 is.

13 BY MR. BLIZZARD:

14 Q. Well, this suggests it's ten times  
15 higher than any competitor. Right?

16 MR. HUTCHINSON: Same objection.

17 THE WITNESS: If it's not clinically  
18 relevant, it doesn't matter if it's 20 times.

19 BY MR. BLIZZARD:

20 Q. So you're back to it doesn't matter.  
21 Right?

22 MR. HUTCHINSON: Same objections,  
23 Counsel, mischaracterization of the witness's  
24 testimony.

25 BY MR. BLIZZARD:

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1 Q. Well, I mean, didn't you just say it  
2 doesn't matter?

3 A. I would -- making a statement about  
4 the tenfold. If it's a message from -- it was Marty  
5 Weisberg saying that particle loss was not  
6 clinically relevant.

7 Q. Well, it seemed like it was, at one  
8 point, going to matter to the French, didn't it?  
9 The French were developing this test, and they said  
10 if you didn't pass the test, you couldn't sell the  
11 product. Right?

12 MR. HUTCHINSON: Objection, calls for  
13 speculation.

14 THE WITNESS: Again, I wasn't  
15 involved in those conversations, but apparently they  
16 were looking at that, yes.

17 BY MR. BLIZZARD:

18 Q. So it mattered to them, didn't it?

19 MR. HUTCHINSON: Same objections.

20 THE WITNESS: Apparently.

21 BY MR. BLIZZARD:

22 Q. And if you couldn't sell it in  
23 France, that would matter to the company too,  
24 wouldn't it?

25 A. It could.